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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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William Suttle Peters

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ORRICK, HERRINGTON & SUTCLIFFE, LLP
IP PROSECUTION DEPARTMENT
4 PARK PLAZA
SUITE 1600
IRVINE, CA 92614-2558

EXAMINER

PATEL, TARLA R

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,604	Applicant(s) PETERS ET AL.	
	Examiner TARLA R. PATEL	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/28/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 4/28/06. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The disclosure is objected to because of the following informalities: Abstract must be presented in separate paper not the front page of foreign document.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 8 and 11-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Yanagi (1,576,397)

Milbocker et al. discloses a method (as normal use of the device of Yanagi) of securing a flexible wrap (21) around a blood vessel, the wrap being generally elongate and having first and second end portions (as shown in figure 1, wrap shown to have elongated shape having first end and second end portion as two ends of element 21), the method including the steps wrapping the flexible wrap around the blood vessel (see figure 1, shown to have flexible wrap around the blood vessel), passing the first end portion of the wrap through a buckle device (10) affixed substantially distally from the first end portion of wrap (see figure 1), adjusting (by moving the wrap 21 by end of wrap would eventually create tension) the tension in the wrap to a desired level by movement of the first end portion of the wrap relative to the buckle device (10), securing together adjacent parts of the wrap (by placing the wrap in area 14) substantially adjacent the blood vessel and removing the buckle device (by just removing the wrap from the buckle device 10).

With respect to claim 2, Yanagi discloses the buckle device includes means to hold the adjacent part of wrap together (see figure 1).

With respect to claims 3-4, Yanagi inherently discloses wrap holds a heart assist device vessel in place against an arterial vessel (as broadly interpreted that the blood vessel runs in arm eventually runs to the heart, therefore a heart assist device vessel in place).

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With respect to claim 8, Yanagi discloses releasable buckle assembly (see figures 2-4).

With respect to claims 11-12, Yanagi discloses the buckle device includes a leg (11) or spring legs (both 17) that pierce the wrap and to clamp the wrap therebetween respectively.

With respect to claims 13-14, Yanagi discloses buckle device includes at least two parallel and spaced apart legs (11) and the method includes adjusting the tension in the wrap until the legs begin to deform towards each other (see figure 1-2) and the wrap includes aortic distance markers and the method includes adjusting the tension in the wrap until the desired aortic circumference is reached (as broadly interpreted the aortic main trunk of artery system includes artery runs in arm as well).

With respect to claim 15, Yanagi discloses the buckle device (10) is adapted to lightly grip the first and second end portions of the wrap so that the wrap may be drawn tight around the vessel and then released (see figure 1) and the limitation of adapted to lightly grip the first and second end portions of the wrap so that the wrap may be drawn tight around the vessel and then released, such limitations have not been considered since it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138.

With respect to claim 16, Yanagi discloses a flexible wrap (21) to be secured around a blood vessel, the wrap being generally elongate and having first and second end portions (as shown in figure 1, wrap shown to have elongated shape having first end and second end portion as two ends of element 21), there being attached to the wrap a

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buckle device (10) through which the second end portion of the wrap may be threaded to allow the wrap to be drawn (see figure 1), adjusting (by moving the wrap 21 by end of wrap would eventually create tension) the tension in the wrap to a desired level by movement of the first end portion of the wrap relative to the buckle device (10), buckle device being removable from the wrap after the end portions thereof have been connected together around the blood vessel (see figure 1).

With respect to claims 17-19, Yanagi discloses the buckle device (10) includes means to hold (by element 11 and 17) overlapping parts of the wrap together, the buckle device is attached to the wrap substantially distally to the second end portion (see figure 1) and the buckle device (10) is attached to the wrap adjacent to the first end portion (see figure 1).

With respect to claim 21, Yanagi discloses wrap for use in securing a vessel to an arterial vessel, the wrap (21) being generally elongate with two end portions (see figure 1) and having a buckle device releasably attached thereto that includes at least a pair of substantially parallel legs (11 and 17) with a gap (gap in between these legs is interpreted as gap required by claim) therebetween through which the two end portions of the wrap can pass (see figure 1).

With respect to claim 22, Yanagi discloses a buckle device (10) for use in securing wrap around an arterial vessel, the wrap (21) being generally elongate and having two end portions (see figure 1), the buckle device (10) including at least a pair of substantially parallel legs (11 and 17) with a gap (gap in between these legs is interpreted as gap required by claim) therebetween through which the two end portions of the wrap can

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pass (see figure 1), wherein at least one the legs is adapted for releasably fixing the wrap, such limitations have not been considered since it has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138. further, Yanagi buckle device (10) is adapted for releasably fixing the wrap.

With respect to claims 23-24, Yanagi discloses the buckle device (10) is adapted for suturing and stapling to the wrap, such limitations have not been considered since it has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138. further, Yanagi’s buckle device (10) is adapted for suturing and stapling to the wrap.

With respect to claim 25, Yanagi discloses the device includes a pair of enlarged ends (12 and 14) adapted to clear suture knots during removal of the device from the secured wrap, such limitations have not been considered since it has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138. further, ends of Yanagi’s buckle device are adapted to clear suture knots during removal of the device from the secured wrap.

With respect to claim 26, Yanagi discloses an enlarged formation in about the middle of one of legs (see figures 2 and 4), which is adapted to allow forceps access between the

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two legs, such limitations have not been considered since it has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138. further the space formation in between the legs (17) would allow forceps access between the two legs.

With respect to claim 27, Yanagi discloses the other leg of the device is formed from two part legs stemming from each of the enlarged end formations, the two part legs having a small clearance between their distal ends (figures 2 and 4).

With respect to claim 28, Yanagi discloses the buckle device (10) includes a third leg (other side of 17) that pierces the wrap.

With respect to claim 29, Yanagi discloses the three legs of the buckle device (10) are all substantially parallel, with the first and second legs being joined at one end of the wrap and the other end of the wrap is passed between the second and third legs and adjusted to the desired wrap tension (see figures 2 and 4).

With respect to claim 30, Yanagi discloses small barbs are included on one of the legs (19), such that as the wrap end is pulled through, the material runs forward over the barb and on pulling back, the barbs snag into the wrap to secure it in position whilst the wrap is secured (see figure 1).

With respect to claim 31, Yanagi's buckle device (10) utilizes spring wire and telltales to indicate the tension developed when pulling on the wrap to secure it around the blood vessel (lines 39-43).

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With respect to claim 32, Yanagi discloses the arms of the buckle are formed (end part of the 19) and sized relative to spring force such that when the wrap is tensioned the arms deflect towards one another (see figures 2 and 4).

With respect to claim 33, Yanagi discloses loops (13) in one side of the parallel legs are provided to secure the buckle to the wrap.

With respect to claim 34, Yanagi discloses bends or a tubular shape in one side of the parallel legs is provided to secure the buckle device to the wrap (14).

With respect to claim 35, Yanagi discloses the buckle is curved to replicate the adjacent curve of a blood vessel (see figures 2 and 4).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 5-6 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagi in view of Millbocker et al. (6,572,534).

Yanagi substantially discloses the invention, see rejection to claims 1-4, 8 and 11-35; however, Yanagi does not disclose the suturing and stapling of wrap.

However, Millbocker et al. teaches a system and method for implanting a cardiac wrap comprising suturing and stitching (column 1 lines 54-56). At the time of the invention was made, it would have been obvious to one having ordinary skill in the art to use the

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suturing to secure the wrap of Yanagi's device, as taught by Millbocker et al. to better secure the wrap.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TARLA R. PATEL whose telephone number is (571)272-3143. The examiner can normally be reached on M-T 6-3.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tarla R Patel/

Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772